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TRANSLATION

## PATENT COOPERATION TREATY

PCT

PCT Application  
PCT/CN2004/000636INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|   |   |   |
|---|---|---|
| Applicant's or agent's file reference<br><br>WZZ041093CP  | FOR FURTHER ACTION  | See Form PCT/IPEA/416   |
| International application No.<br><br>PCT/CN2004/000636  | International filing date (day/month/year)<br><br>14. June. 2004 (14.06.2004) | Priority date (day/month/year)<br><br>16. July. 2003 (16.07.2003) |
| International Patent Classification (IPC) or national classification and IPC<br><br>C07J7/00, C07J71/00 |   |   |

|   |   |
|---|---|
| Applicant<br><br>SHANGHAI INSTITUTE OF ORGANIC CHEMISTRY, CHINESE ACADEMY OF SCIENCE, et al   |   |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 3 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic _____ containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> |   |
| Date of submission of the demand<br><br>09. Dec. 2004 (09. 12. 2004)  | Date of completion of this report<br><br>09. August. 2005 (09. 8. 2005)   |
| Name and mailing address of the IPEA/CN<br><br>The State Intellectual Property Office, the P.R.China,<br>6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China<br>100088<br>Facsimile No. 86-10-62019451  | <p>Authorized officer<br/><br/> <br/> Xiao Peng<br/> (86-10)62085625</p> <p>Telephone No.</p> |

## Box No. I Basis of the report

## 1. With regard to the language, this report is based on:

the international application in the language in which it was filed

a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

international search (Rules 12.3(a) and 23.1(b))

publication of the international application (Rule 12.4(a))

international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages \_\_\_\_\_ as originally filed/furnished

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages \_\_\_\_\_ as amended (together with any statement) under Article 19

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages \_\_\_\_\_ as originally filed/furnished

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_

the claims, Nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_

the claims, Nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/CN2004/000636

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement:

|                               |              |     |
|-------------------------------|--------------|-----|
| Novelty (N)                   | Claims 1-4   | YES |
|                               | Claims _____ | NO  |
| Inventive step (IS)           | Claims 1-4   | YES |
|                               | Claims _____ | NO  |
| Industrial applicability (IA) | Claims 1-4   | YES |
|                               | Claims _____ | NO  |

## 2. Citations and explanations (Rule 70.7)

## 1. Prior Art

The Written Opinion is based on the documents cited in the International Search Report.

D1: CN A 1341603

D2: CN C 1061985

D3: CN A 1299821

D4: CN C 1055930

D5: US A 4753932

D6: Chinese Journal of Pharmaceuticals, Vol.31, No.5, 2000, HAN Guangdian et al, "Development of Total Synthesis of Contraceptive Steroid Drugs in China", p231-236

## 2. Novelty

The method claimed by claims 1-4, where the steroid sapogenin is decomposed, and then without separation or purification, subjecting directly to the next "one-pot-reaction" of oxidation, reduction and hydrolysis, are not disclosed in any of the cited documents and thus are considered to fulfil the requirements of Art. 33(2) PCT with respect to the cited prior art.

## 3. Inventive Step

Document D1 is considered to be the closest prior art. But in this document, the decomposed product of steroid soapgenin is the ester of 16-dehydropregneneol and acetic acid, and then it is subject to the oxidation, reduction and hydrolysis after further separation or purification, while, the method as claimed in claims 1-4 is that the steroid sapogenin is decomposed, and then without separation or purification, it is subjected directly to the next "one-pot-reaction" of oxidation, reduction. The method as claimed in claims 1-4 omitted reaction steps, and this omission are not obvious to the people skilled in the art. Therefore, the subject matter of claims 1-4 is considered to fulfil the requirements of Art. 33(3) PCT with respect to the cited prior art.

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